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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,040	03/01/2002	Joseph C. Cauthen	08442.0002-04	8078

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
CHATTOPADHYAY, URMI	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,040	CAUTHEN, JOSEPH C.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *102-107,109-133,137-139,141,142,145-149,151-175 and 179-181* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *102-107,109-133,137-139,141,142,145-149,151-175 and 179-181* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. The request filed on February 24, 2006 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 10/085,040 is acceptable and a RCE has been established. An action on the RCE follows.

Response to Amendment

2. The amendment filed February 24, 2006 has been entered. The changes to the claims have been approved. Claims 108, 134-136, 140, 143, 144, 150, 176-178 and 182 have been canceled. All pending claims 102-107, 109-133, 137-139, 141, 142, 145-149, 151-175 and 179-181 are being considered for further examination on the merits.

Response to Arguments

3. Applicant's arguments, see pages 12-13 of the amendment filed February 24, 2006, with respect to the rejection(s) of claim(s) 102-107, 109-133, 137-139, 141, 142, 145-149, 151-175 and 179-181 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 141, 142, 148, 149, 154-156, 160, 162, 172-175 and 179-181 are rejected under 35 U.S.C. 102(e) as being anticipated by of Gilson (USPN 5,904,703, as cited in applicant's IDS).

Gilson discloses an occluder device that is structurally capable of being used to treat an intervertebral disc wall with all the elements of claim 141. See Figure 14 for the device (60) comprising a main body portion (6) and an extension (5) having an axis projecting along a respective reference plane, which extends substantially laterally from the main body portion (6). See column 6, lines 20-23 for the extension (5) being constructed such that the axis can flexibly deflect from its respective reference plane. See Figure 3 for at least one receptacle (11) that is configured such that it is capable of receiving a fixation element.

Claim 142, see Figure 3 for the receptacle (11) comprising a slot.

Claim 148, see Figure 6, columns 2-3, lines 67-2, and column 5, lines 38-48 for the main body portion (6) being shaped such that it is capable of forming a compatible fit with the edges of at least a portion of an aperture in an intervertebral disc wall.

Claim 149, see Figure 3 for the extension (5) being of substantially uniform thickness.

Claims 154 and 155, see column 4, lines 43-44 and 54-67 for the main body portion (6), the extension (5) and receptacle (11) being formed as a unitary device.

Claims 156 and 162, see column 2, lines 43-44 and column 4, lines 30-31 for the device (60) comprising a biocompatible polymeric material.

Claim 160, see column 2, lines 61-62 for the device (60) comprising a biodegradable substrate.

Claim 172, see Figure 14, columns 2-3, lines 64-2 and column 6, lines 20-23 for the device (60) being flexibly resilient.

Claim 173, see column 4, lines 55-58 for at least a portion of the device (60) being porous.

Claim 174, see column 4, lines 44-51 for the receptacle (11) portion of the device (60) being non-porous.

Claim 175, see Figures 6 and 14, columns 2-3, lines 64-2, column 5, lines 26-32 and column 6, lines 20-23 for the extension (5) being reversibly deformable to allow, in use, insertion into an aperture of an intervertebral disc and subsequent expansion from its compressed configuration, thereby conforming the device (60) to the shape of a portion of the inner wall of an annulus. Although Gilson does not disclose using the device in this manner, the device is structurally capable of being used in this manner.

Claim 179, see Figure 14 for first and second extensions (5).

Claims 180 and 181, see Figure 14 for the respective axes of the first and second extensions (5) lying in the same reference plane when the extensions (5) are undeflected.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 102-133, 137-139, 145-147, 151-153, 157-159, 161 and 163-171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilson in view of Bao et al. (USPN 6,224,630 as cited in applicant's IDS).

Gilson discloses an occluder device that is structurally capable of being used to treat an intervertebral disc wall with all the elements of claim 141, but is silent to the device further comprising biodegradable surgical sutures comprising a knot, as required by claims 145-147, barbs, tension bands and staples, as required by claims 151-153, and a polymeric mesh, as required by claim 165. Bao et al. teaches an occluder device for biological apertures, wherein the device can be used for the treatment of an intervertebral disc wall (column 2, lines 58-61). Biodegradable sutures, staples, and barbs (tines), as well as polymeric meshes, are disclosed as anchoring means in order to enhance short-term fixation of the device to the disc annulus, which will prevent migration of the device. See column 14, lines 15-30. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Bao et al. to modify the occluder device of Gilson by including anchoring means in the form of biodegradable surgical sutures (claims 145 and 146), which also provide as tension bands (claim 152), barbs (claim 151), staples (claim 153), or polymeric meshes (claim 165) to the device (60) in order to enhance short-term fixation and prevent migration of the device (60). It is obvious that the sutures would comprise at least one knot because it is well known to knot sutures to prevent them from coming out or pulled apart (claim 147). When the device (60) of Gilson, as

modified by Bao et al., is used to treat an intervertebral disc wall, short-term fixation will be to the disc annulus.

Gilson discloses that the occluder device (60) is made from a compressible, porous polymeric foam in column 4, lines 30-31 and 55-58. Bao et al. teaches the occluder device also being made from a compressible, porous polymeric foam in column 3, lines 15-19 and column 5, lines 36-42. The foam can be made from bioresorbable collagen fibers (claims 157 and 167; column 6, lines 40-43), interwoven biocompatible polymeric fibrils that by nature provide a membrane, fabric or sheet (claims 158, 159, 163, 164 and 166; column 7, lines 34-37), or ePTFE (claim 161; column 5, lines 56-57). These materials can be made sufficiently porous to permit tissue ingrowth into the material from surrounding tissue of the implant site. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Bao et al. to make the polymeric foam material of the device (60) of Gilson from the materials required by claims 157-159, 161, 163, 164, 166 and 167 in order to make the foam with sufficient porosity to permit tissue ingrowth into the material from surrounding tissue of the implant site. When the device (60) of Gilson, as modified by Bao et al., is used to treat an intervertebral disc wall, the material of the device will facilitate regeneration of disc tissue (claim 169) by promoting tissue ingrowth from the surrounding annulus. Bao et al. also teaches making the foam from a hygroscopic material in order to initially secure the expanded device within the aperture (claim 168; column 3, lines 8-10), and including a bioactive silica-based material or a growth factor to the occluder device material in order to actively facilitate tissue ingrowth and/or improve the biocompatibility of the device (claims 170 and 171; column 9, lines 12-40).

Gilson discloses an occluder device that is structurally capable of being used to treat an intervertebral disc wall with all the elements of claim 102, but is silent to at least one fixation element configured to extend at least partially into annular tissue. See Figure 14 for the device (60) comprising a main body portion (6) and an extension (5) having an axis projecting along a respective reference plane, which extends substantially laterally from the main body portion (6). See column 6, lines 20-23 for the extension (5) being constructed such that the axis can flexibly deflect from its respective reference plane. Bao et al. teaches an occluder device for biological apertures, wherein the device can be used for the treatment of an intervertebral disc wall (column 2, lines 58-61). Fixation elements in the form of biodegradable sutures, staples, and barbs (tines), as well as polymeric meshes, are disclosed as extending at least partially into annular tissue in order to enhance short-term fixation of the device to the disc annulus, which will prevent migration of the device. See column 14, lines 15-30. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Bao et al. to modify the occluder device of Gilson by including fixation elements configured to extend at least partially into annular tissue and in the form of biodegradable surgical sutures (claims 103 and 104), which also provide as tension bands (claim 110), barbs (claim 109), staples (claim 111), or polymeric meshes (claim 123) to the device (60) in order to enhance short-term fixation and prevent migration of the device (60). It is obvious that the sutures would comprise at least one knot because it is well known to knot sutures to prevent them from coming out or pulled apart (claim 105). When the device (60) of Gilson, as modified by Bao et al., is used to treat an intervertebral disc wall, short-term fixation will be to the disc annulus.

Claim 106, see Figure 6, columns 2-3, lines 67-2, and column 5, lines 38-48 for the main body portion (6) being shaped such that it is capable of forming a compatible fit with the edges of at least a portion of an aperture in an intervertebral disc wall.

Claim 107, see Figure 3 for the extension (5) being of substantially uniform thickness.

Claim 112, see column 4, lines 43-44 and 54-67 for the main body portion (6) and the extension (5) being formed as a unitary device.

With respect to claim 113, when the fixation element in the from of polymeric meshes of Bao et al. are applied to the exterior surface of the device (60) of Gilson, the main body portion (6), extension (5) and fixation element will be formed as a unitary device.

Claims 114 and 120, see column 2, lines 43-44 and column 4, lines 30-31 for the device (60) comprising a biocompatible polymeric material.

Claim 118, see column 2, lines 61-62 for the device (60) comprising a biodegradable substrate.

Claim 130, see Figure 14, columns 2-3, lines 64-2 and column 6, lines 20-23 for the device (60) being flexibly resilient.

Claim 131, see column 4, lines 55-58 for at least a portion of the device (60) being porous.

Claim 132, see column 4, lines 44-51 for the sleeve (11) portion of the device (60) being non-porous.

Claim 133, see Figures 6 and 14, columns 2-3, lines 64-2, column 5, lines 26-32 and column 6, lines 20-23 for the extension (5) being reversibly deformable to allow, in use, insertion into an aperture of an intervertebral disc and subsequent expansion from its compressed

configuration, thereby conforming the device (60) to the shape of a portion of the inner wall of an annulus. Although Gilson does not disclose using the device in this manner, the device is structurally capable of being used in this manner.

Claim 137, see Figure 14 for first and second extensions (5).

Claims 138 and 139, see Figure 14 for the respective axes of the first and second extensions (5) lying in the same reference plane when the extensions (5) are undeflected.

With respect to claims 115-117, 119, 121, 122 and 124-129, see rejection of claims 157-159, 161, 163, 164 and 166- 171, supra.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Urmi Chattopadhyay
Art Unit 3738

David J. Isabella
Primary Examiner